REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1, 39-47, 49-62, 66-68, 71, 72, 76 and 77 presently appear in this application, with claims 51-62, 66-68, 71, 72, 76 and 77 being withdrawn from consideration, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

It is understood that, upon allowance of an elected product claim, nonelected product claims which depend from the allowable product claim or otherwise include all the limitations of the allowable product claim would be rejoined under rejoinder practice pursuant to MPEP 821.04.

The disclosure has been objected to because the title of the invention is not considered descriptive. The title is now replaced with an appropriate new title, thereby obviating this objection.

Reconsideration and withdrawal of this objection are therefore respectfully requested.

Claim 27 and claims dependent therefrom have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The examiner holds that it is not clear if the claim recitation limits the type of folding factor or the number of

folding factor copies. The examiner further holds that the recited closed "consisting of" language is inconsistent with the recited plurality being unlimited and open in nature. This rejection is respectfully traversed.

The feature recited in claim 27 is now incorporated into amended claim 1. For clarification, the recitation of the folding factor being a chaperonin consisting of a plurality of chaperonin subunits is intended to be directed to chaperonins within the genus of folding factors. As disclosed on page 7 of the present specification, folding factors are generally classified into molecular chaperones and foldases. One group of molecular chaperones, which also includes other groups such as heat shock proteins and prefoldins, is chaperonins. As a chaperonin is a complex protein composed of a plurality of subunits, the "consisting of a plurality of chaperonin subunits" language was merely used to provide antecedent basis for dependent claims reciting for the chaperonin subunits. Applicants have amended the claims to recite "comprising a plurality of chaperonin subunits" if the examiner finds this more preferable.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1, 25-30, 33 and 34 have been rejected under 35 U.S.C. §102(b) as being anticipated by Fersht et al., WO 00/75346. This rejection is respectfully traversed.

In order to better understand the difference between the immunogen in the presently claimed immunizing composition and the fusion proteins of Fersht, the three structural domains of chaperonins are first discussed. In general, chaperonins consists of multimeric two-ring assemblies that contain a central cavity. They are divided into structurally distinct classes, i.e., "group I chaperonins" found in prokaryotic cells and endosymbiotic organelles and "group II chaperonins" occurring in Archaea and Eukarya (see page 598, right column, 1st full paragraph to paragraph bridging pages 598 and 599 of Spiess et al., *Trends Cell Biol.*, 14(11):598-604 (2004), and the introduction section on page 263 of Klumpp et al., *Cell* 91:263-270 (1997), copies of which are attached hereto). Both group I and group II chaperonin subunits share a similar basic structure that consists of three domains: an equatorial domain (residues 6-133 and 409-523 in *E. coli* GroEL), an intermediate domain (residues 1-5, 134-190, 377-408, and 524-548 in *E. coli* GroEL), and an apical domain (residues 191-376 in *E. coli* GroEL). See lines 7 to 11 on page 2 of Fersht et al. The equatorial domain forms the structural foundation of the cylinder providing the

major contacts between the subunits both within and between rings; see for example page 744, right column, first full paragraph of Fenton et al., *Protein Science* 6:743-760 (1997), a copy of which is attached hereto.

As the examiner asserts, Fersht discloses a fusion protein comprising a fragment of GroEL and a protein of interest. Specifically, the fragment has an amino acid sequence of at least amino acid residues 230-271 of GroEL, preferably the 191-375 fragment of GroEL (see e.g., lines 17 to 21 on page 7, lines 4 to 9 on page 8, line 24 on page 10 to line 16 on page 11, and Examples 1 and 2). This indicates that the fragment corresponds mainly to an apical domain which forms the end portion of a chaperonin cylinder and alone cannot form a multiple ring structure. The fusion protein disclosed in Fersht does not contain a chaperonin subunit capable of forming a ring structure. Fersht's disclosed fusion protein cannot form a ring structure and therefore cannot accommodate the protein of interest in the chaperonin ring as presently recited in the claims.

Furthermore, the fusion protein of Fersht has only one chaperonin subunit fragment and therefore does not meet the requirement of two or more chaperonin subunits serially linked to one another via peptide bonds, as presently recited in the claims.

Accordingly, Fersht does not and cannot anticipate the presently claimed immunizing composition.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1, 25-30, 33 and 34 have been rejected under 35 U.S.C. §102(b) as being anticipated by Scholz et al., WO03/000878. This rejection is respectfully traversed.

With due respect to the examiner, the examiner has misinterpreted FKBP chaperone, which is FKBP-type Peptidyl prolyl cis-trans isomerase (FKBP-type PPIase), as a chaperonin. While Scholz discloses a fusion protein comprising a FKBP-type PPIase (FKBP chaperone) and a protein of interest, this is not the same as a fusion protein of a chaperonin (e.g., GroEL) and a protein of interest (antigen protein). FKBP-type PPIase is not a chaperonin and therefore Scholz simply does not and cannot anticipate the presently claimed immunizing composition.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1 and 23-50 have been rejected under 35 U.S.C. §102(b) as being anticipated by Furutani et al., WO 02/052,029, in light of Furutani et al., US 7,276,355 (the English language equivalent of WO'029). This rejection is respectfully traversed.

There is no disclosure in Furutani of an immunizing composition which includes an adjuvant. Accordingly, Furutani cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 63-65 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Furutani et al., WO 02/052,029, in view of Scholz et al., WO 03/000878 and Harlow et al. (1988). The examiner states that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add an adjuvant to the fusion protein compositions of Furutani because Scholz teaches that chaperonin fusion proteins can be used as immunogens for vaccines. This rejection is respectfully traversed.

As discussed above, Scholz does not teach "chaperonin" fusion proteins but rather teaches an FKBP-type PPIase. Accordingly, Scholz does not teach that chaperonin fusion proteins can be used as immunogens for vaccines and there is simply no suggestion or motivation in Furutani alone to use a chaperonin fusion protein as an immunogen or in an immunizing composition that further comprises an adjuvant.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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